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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/032,254	12/21/2001	Lewis A. Chodosh	22253-70422	6647

7590 03/10/2004

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EXAMINER	
RAWLINGS, STEPHEN L	
ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 03/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/032,254	CHODOSH ET AL.	
	Examiner	Art Unit	
	Stephen L. Rawlings, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-47 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-47 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Claims 1-47 are pending in the application and are currently subject to restriction.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claims 1 and 2, drawn to a purified protein, classified in class 530, subclass 350.

Group II. Claims 3, 4, 39, 40, 42, 44, and 46, drawn to an isolated nucleic acid molecule, a vector, a recombinant cell, classified in class 536, subclass 23.1 or 23.5, class 435, subclass 320.1, and class 435, subclass 325+, respectively.

Group III. Claims 5, 7, 9, 17, and 21, drawn to a method comprising delivering to a target cell an effective amount of a protein, classified in class 514, subclass 12.

Group IV. Claims 6, 8, 16, and 20, drawn to a method comprising delivering to a target cell an effective amount of a nucleic acid molecule, classified in class 514, subclass 44.

Group V. Claims 10, 12, and 18, a method comprising delivering to a target cell an effective amount of an antagonist of activation or function of a protein, which cannot be classified because the chemical and biologic nature of the antagonist has not been specified.

Group VI. Claims 11, 19, and 43, insofar as the claims are drawn to an antisense nucleic acid molecule and a method comprising delivering to a

target cell an effective amount of an antisense nucleic acid molecule, classified in class 514, subclass 44.

Group VII. Claims 11 and 19, insofar as the claims are drawn to a method comprising delivering to a target cell an effective amount of an anti-Pnck molecule, classified, for example, in class 424, subclass 139.1.

Group VIII. Claims 13, 15, 22, and 24, a method comprising delivering to a target cell an effective amount of an agonist of activation or function of a protein, which cannot be classified because the chemical and biologic nature of the agonist has not been specified.

Group IX. Claims 14, 23, and 25, a method comprising delivering to a target cell an effective amount of an agonist of activation or function of a nucleic acid molecule, which cannot be classified because the chemical and biologic nature of the agonist has not been specified.

Group X. Claims 26-31 and 37, insofar as the claims are drawn to a method comprising detecting and measuring the amount of a protein, classified, for example, in class 435, subclass 7.1.

Group XI. Claims 26-31, insofar as the claims are drawn to a method comprising detecting and measuring the amount of a nucleic acid molecule, classified, for example, in class 435, subclass 6.

Group XII. Claims 32-36, insofar as claims are drawn to a method comprising measuring the amount of a protein in a cell, treating the cell with a compound, measuring the amount of the protein in the treated cell, and comparing the results of the measurements, classified, for example, in class 435, subclass 7.1.

Group XIII. Claims 32-36, insofar as claims are drawn to a method comprising measuring the amount of a nucleic acid molecule in a cell, treating the cell with a compound, measuring the amount of the nucleic acid molecule in the treated cell, and comparing the results of the measurements, classified, for example, in class 435, subclass 6.

Group XIV. Claims 38, drawn to a method comprising measuring the activity of a protein in a patient and predicting the appropriate therapy for the patient, classified, for example, in class 435, subclass 194.

Group XV. Claim 41, drawn to an antibody, classified in class 530, subclass 387.1+.

Group XVI. Claims 45 and 47, drawn to a transgenic cell or animal, classified, for example, in class 800, subclass 13.

3. The inventions are distinct, each from the other because of the following reasons:

The inventions in groups I, II, XV, and XVI are disclosed as biologically and chemically distinct, unrelated in structure and/or function, and/or made by and/or used in different methods, and therefore the claimed products are distinct.

The inventions in groups III-XIII are disclosed as materially different methods that differ at least in objectives, method steps, reagents and/or doses and/or schedules used, response variables, assays for end products and/or results, and criteria for success, and therefore the claimed methods are distinct. For example, the inventions of groups III-IX are materially different methods in that the methods comprise delivering to a target cell substances, which are biologically and chemically distinct, and/or structurally and/or functionally distinct, whereas the inventions of groups X-XIII most notably differ from one another and from the inventions of groups III-IX in objective and process, e.g., groups X and XII involve measuring a protein, whereas groups XI and XIII

involve measuring a nucleic acid molecule, and practicing the invention of groups X and XI may result in diagnosis, whereas practicing the inventions of groups XII and XIII may result in identifying a compound that modulates the expression of a protein or a nucleic acid, respectively. As further evidence the inventions of groups III-XIII are distinct, the search that would be required to consider each would not the same or co-extensive with the search required to consider any other.

Inventions in groups I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed, namely the protein can be used in a materially different process of using that product, such the process of producing an antibody that binds to the protein by immunizing an animal with the protein.

Inventions in groups II and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed, namely the nucleic acid molecule can be used in a materially different process of using that product, such the process of detecting a nucleic acid molecule to which the claimed nucleic acid molecule binds by Northern analysis.

Inventions in groups XV and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed, namely the antibody can be used in a materially different process of using that product, such the process of purifying the protein to which the antibody binds by affinity chromatography.

The inventions in group I and groups IV-XIII are not at all related because the products of group I are not specifically used in any of the steps of the claimed methods in groups IV-XIII.

The inventions in group II and groups III and V-XIII are not at all related because the products of group II are not specifically used in any of the steps of the claimed methods in groups III and V-XIII.

The inventions in group XV and groups III-VI and VIII-XIII are not at all related because the products of group XV are not specifically used in any of the steps of the claimed methods in groups III-VI and VIII-XIII.

The inventions in group XVI and groups III-XIII are not at all related because the products of group XVI are not specifically used in any of the steps of the claimed methods in groups III-XIII.

4. Because these inventions are distinct for the reasons given above and also because the search required for any one group is not required for any other group and/or the inventions have acquired a separate status in the art as shown by their different classification or their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

6. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance,

whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is

(571) 272-0836. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne L. Eyler, Ph.D. can be reached on (571) 272-0871. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Stephen L. Rawlings, Ph.D.
Examiner
Art Unit 1642

slr
February 23, 2004

YVONNE EYLER, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600